

July 23, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.83

Subject: Export of Serials Before Completion of Serial Release Testing

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidance concerning the export of veterinary biological products before completion of serial release testing.

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 800.83 dated May 4, 1994.

III. BACKGROUND

Under 9 CFR 113.6 and 116.7, a firm may not export a product serial for marketing prior to test completion and serial release. In the past, APHIS has occasionally granted exemptions to these regulations to facilitate concurrent testing in a foreign country. To further expedite such testing, APHIS will now permit the shipment of samples of a completed serial to foreign facilities for concurrent testing under the conditions given below.

IV. GUIDELINES

A. Products for Further Manufacture

APHIS does not require testing prior to release of a serial for further manufacture (FFM), except when the Outline of Production specifically includes such a test requirement. The policy presented in this memorandum is not applicable to FFM products.

B. Products in Final Form, Composition, and Containers

1. *Entire serials* - A firm may export a product serial only after tests required by APHIS have been satisfactorily completed and APHIS has released the serial for shipment. (See Veterinary Services Memorandum 800.53 for information on the policy and procedures concerning the release of biological products.)

2. *Serial samples* - Outlines of Production may include a statement permitting the firm to export serial samples sufficient for testing prior to serial release. The outline should specify the quantity of serial sample the firm will ship and the name and location of the recipient facility. This information should be included in the "Post preparatory steps" section of the Outline of Production as appropriate.

V. OUTLINES OF PRODUCTION

All current Outlines of Production for applicable products and future Outlines of Production written for such products should conform with this memorandum.

/s/ Thomas E. Walton for

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